REMARKS

Claims 54, 56, 60-64, 72, 73, 76, 77 and 79-89 are pending. Claims 1-53, 55, 57-59, 65-71, 74, 75 and 78 have been canceled, claims 54 and 82 have been amended, and the following remarks presented.

Claim Rejections under 35 U.S.C. 112

Claims 54, 56, 60-64, 72, 73, 76 and 81-86 are rejected under 35 U.S. C. 112, second paragraph as being indefinite. The Examiner states that "it is not at all clear whether the tumor-specific vaccines is the polynucleotide comprising or the antigen."

This rejection is respectfully traversed. Applicant has amended claims 54 and 82 at line 3 to include ", said polypeptide being useful as a B-cell lymphoma tumor-specific vaccine..." By including these words, Applicant has made it clear that under these claims the vaccine is the polypeptide, and not the polynucleotide.

Further, the Examiner states that "it is unclear if the vaccine is useful as a tumor-specific vaccine for tumor types other than B-cell lymphoma tumor types." It seems that it should be sufficient for clarity that the polypeptide is derived from a specific B-cell lymphoma surface immunoglobulin antigen. A person skilled in the art would not be confused or believe that specificity for another tumor or tumor type is being claimed, and no such concept is suggested in the specification. A person skilled in the art would not consider the antigen to be specific to anything else, absent further information, even if another binding counterpart were known. If the polypeptide is taken from the surface antigen, then it would certainly be specific for that surface antigen. However, to help move prosecution forward, Applicant has inserted the phrase "B-cell lymphoma" in front of the word "tumor" wherever necessary to further emphasize the specificity of the polypeptide as a vaccine. The term now is "B-cell lymphoma tumor-specific vaccine." Applicant has avoided using the suggested term "B-cell lymphoma-specific vaccine" because this term would not have differentiated between tumors. It should be clear that each is presumed to

differ from any other antigen taken from another B-cell lymphoma tumor. B-cell lymphoma tumor antigens are considered in the art to be unique. Accordingly, the inclusion of this language into the claim is not considered to introduce a further limitation.

Claims 82-86 and 89 are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "the polypeptide linker." This rejection is respectfully traversed. Applicant has amended the claim to recite "a" polypeptide linker.

Claims 54, 56, 60-64, 72, 73, 76, 77, 79-89 are rejected under 35 U.S.C. 112, 1st paragraph. The Examiner states on page 10 of the Office Action that the specification cannot be reasonably extrapolated to enable the scope of the claims because one of skill in the art could not predict that (i) polynucleotides that encode any portion of a B-cell lymphoma surface immunoglobulin antigen, including any two domains or any portion of the V_H region would be useful as a B-cell lymphoma tumor-specific vaccine or (ii) that any size linker would produce functional idiotypes useful as a tumor-specific vaccine. In defense of this position the Examiner points out "the art teaches that protein chemistry is one of the most unpredictable fields."

First Aspect

The specification provides no guidance on structure or residues that are critical to the function of the invention as claimed in the preservation of the idiotypes of the surface immunoglobulin molecule.

Second Aspect

The Examiner states that one skilled in the art could not predict that (i) "any size linker would produce functional idiotypes useful as a tumor-specific vaccine." (ii) "It is clear (in view of Klausner) that one would not expect that any linker of 1-50 amino acids would function as claimed with a reasonable expectation of success." (iii) In view of the unpredictability of protein chemistry and antibody modification and the lack of guidance with regard to these issues, such as working examples…would preserve idiotypes, that short linker segments would function as claimed." Therefore undue experimentation allegedly would be required.

Applicant respectfully traverses this rejection. No experimentation is required to determine which linker is the correct linker, the optimal linker or is the right length, and there is no reason to conduct a Wands type of inquiry. The specification at paragraph [0036] teaches that "a linker can be between 1 and about 50 residues, sometimes between 3 and 25 residues; and at paragraph [0037] that the linker can be between 2 and 12 different amino acids." Further, at paragraph [0111] the specification teaches "selection of (1) appropriate linkers and (2) the transient expression system, as described herein, ensure that the scFv molecules are secreted by the plant cells in a form that is folded in solution, but more than that, it is folded in a conformation that resembles and mimics native IgV region domains on the subject's tumor cells that provided the genetic material for the scFv. **The scFv product is readily identified as the predominant secreted protein species in those plant cells into which it has been successfully incorporated,** permitting simple selection and straightforward, rapid purification for the uses described herein, preferably as a vaccine composition." These statements teach that the epitope/linker combination is selected by the host plant that produces an ScFv that folds properly and a conformation that resembles the native IgV region.

The claimed invention concerns a polynucleotide that encodes a "tumor-specific" vaccine. The polynucleotide is taken from the specific tumor for which the vaccine is intended. A randomized linker library is used. Hundreds or even thousands of dual-domain polypeptides are encoded. Each polypeptide probably having a different linker, the linkers differing in length and amino acid sequence composition. They are then grown in a plant, and the vaccine is chosen from among those in the plants exhibiting the best expression. Each differs by the linker configuration.

If the Examiner maintains this set of rejections, Applicant requests that in the next office action the Examiner point out specifically which word or word group in each claim the Examiner believes to exceed the scope of the specification, in addition to the Examiner's

reasoning. Further, such disputes can often be resolve quickly if the Examiner suggests a possible fix.

Claims 54, 56, 60-64, 72, 73, 76, 81-89 are rejected under 35 U.S.C. 112, 1st paragraph for lack of enablement. The Examiner seems to be saying that without qualifying language the claim is saying that it can be a vaccine against any tumor. It appears that this rejection has been obviated by the insertion of qualifying language into the claims to show that it is a "B-cell lymphoma tumor-specific vaccine."

In view of the amendments and comments above, the rejections have been overcome. Reconsideration, withdrawal of the rejections and early indication of allowance are respectfully requested. If any issues remain, the examiner is encouraged to telephone the undersigned.

If needed, applicants petition for an extension of time under the provisions of 37 CFR 1.136(a) for sufficient time to accept this response. The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No. 500933.

Respectfully submitted,

/Thomas Gallegos/

Thomas R Gallegos
Reg No. 32,692

Thomas R. Gallegos
Large Scale Biology Corporation
3333 Vaca Valley Parkway, Suite 1000
Vacaville, CA 95688
Tel.: (707) 469-2307
FAX.: (707) 446-3917
E-MAIL tom.gallegos@lsbc.com